

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

|  |   |  |
|--|---|--|
| Applicant's or agent's file reference<br><b>1662/58676</b> | <b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below. |  |
| International application No.<br><b>PCT/US 03/ 13002</b>   | International filing date (day/month/year)<br><b>23/04/2003</b>   | (Earliest) Priority Date (day/month/year)<br><b>23/04/2002</b> |
| Applicant<br><b>TEVA PHARMACEUTICAL INDUSTRIES LTD.</b>    |   |  |

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 7 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

contained in the international application in written form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2.  **Certain claims were found unsearchable** (See Box I).

3.  **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

the text is approved as submitted by the applicant.

the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

the text is approved as submitted by the applicant.

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. \_\_\_\_\_

as suggested by the applicant.

because the applicant failed to suggest a figure.

because this figure better characterizes the invention.

None of the figures.

## INTERNAL SEARCH REPORT

Internal Application No

PCT/US2003/13002

A. CLASSIFICATION OF SUBJECT MATTER  
 IPC 7 A61K9/14 A61K31/53

A. Classification to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
 IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, MEDLINE, BIOSIS, CHEM ABS Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |
|----------|--|-----------------------|
| Y        | WO 96 17611 A (WELLCOME FOUND ;HISKETT SIMON PHILIP (GB); TAYLOR SUSAN ANN (GB))<br>13 June 1996 (1996-06-13)<br>cited in the application<br>page 5, line 25 – line 27<br>example 1<br>--- | 1-26                  |
| Y        | ES 8 604 019 A (NIPPON SHINYAKU CO LTD)<br>1 June 1986 (1986-06-01)<br>page 1, line 13 – line 22<br>page 6, line 29 –page 7, line 14<br>page 9, line 9 – line 29<br>examples<br>---        | 1-26                  |

 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

## \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*&\* document member of the same patent family

Date of the actual completion of the international search

4 August 2003

Date of mailing of the international search report

23/10/2003

Name and mailing address of the ISA  
 European Patent Office, P.B. 5818 Patentlaan 2  
 NL - 2280 HV Rijswijk  
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl  
 Fax: (+31-70) 340-3016

Authorized officer

Giménez Miralles, J

## INTERNAL SEARCH REPORT

Internal Application No

PCT/US 03/13002

## C.(Continuation) DOCUMENTS CONSIDERED RELEVANT

| Category | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No. |
|----------|---|-----------------------|
| A        | WO 97 00681 A (WELLCOME FOUND ;FLOYD ALISON GREEN (US); JAIN SUNIL (US))<br>9 January 1997 (1997-01-09)<br>cited in the application examples<br>---   | 1-26                  |
| A        | WO 01 22938 A (VERRECK GEERT ;BAERT LIEVEN (BE); JANSSEN PHARMACEUTICA NV (BE))<br>5 April 2001 (2001-04-05)<br>page 39, line 17 - line 34<br>page 41, line 7 - line 8<br>page 75, line 11 - line 18<br>----- | 1-26                  |

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

Continuation of Box I.1

Although claims 25 and 26 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

-----

Continuation of Box I.1

Claims Nos.: 25,26

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

**INTERNATIONAL SEARCH REPORT**International application No.  
US 03/13002**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: 25, 26  
because they relate to subject matter not required to be searched by this Authority, namely:  
see FURTHER INFORMATION sheet PCT/ISA/210
2.  Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2003/13002

| Patent document cited in search report |   | Publication date | Patent family member(s)  |  | Publication date   |
|--|---|------------------|--|--|--|
| WO 9617611                             | A | 13-06-1996       | AT 213633 T<br>AU 696406 B2<br>AU 4121196 A<br>BR 9509975 A<br>CA 2207284 A1<br>CN 1174505 A<br>CZ 9701717 A3<br>DE 69525649 D1<br>DE 69525649 T2<br>EP 0797441 A1<br>ES 2172600 T3<br>FI 972434 A<br>WO 9617611 A1<br>HU 77367 A2<br>JP 2977284 B2<br>JP 10510255 T<br>NO 972623 A<br>NZ 296573 A<br>PL 320560 A1<br>RU 2160106 C2<br>US 5861179 A  |  | 15-03-2002<br>10-09-1998<br>26-06-1996<br>09-06-1998<br>13-06-1996<br>25-02-1998<br>12-11-1997<br>04-04-2002<br>05-09-2002<br>01-10-1997<br>01-10-2002<br>09-06-1997<br>13-06-1996<br>30-03-1998<br>15-11-1999<br>06-10-1998<br>06-08-1997<br>22-08-1997<br>13-10-1997<br>10-12-2000<br>19-01-1999                             |
| ES 8604019                             | A | 01-06-1986       | ES 8604019 A1  |  | 01-06-1986   |
| WO 9700681                             | A | 09-01-1997       | AT 228844 T<br>AU 6415796 A<br>DE 69625200 D1<br>DK 833640 T3<br>WO 9700681 A1<br>EP 0833640 A1<br>ES 2188766 T3<br>JP 11507936 T<br>PT 833640 T<br>US 5942510 A   |  | 15-12-2002<br>22-01-1997<br>16-01-2003<br>24-03-2003<br>09-01-1997<br>08-04-1998<br>01-07-2003<br>13-07-1999<br>30-04-2003<br>24-08-1999   |
| WO 0122938                             | A | 05-04-2001       | AU 1046200 A<br>AU 7512700 A<br>BG 105419 A<br>BG 106521 A<br>BR 0014271 A<br>BR 9915176 A<br>CA 2351203 A1<br>CA 2384188 A1<br>CN 1376057 T<br>CN 1325387 T<br>CZ 20011532 A3<br>CZ 20020907 A3<br>EE 200100253 A<br>EE 200200151 A<br>WO 0122938 A1<br>WO 0027828 A2<br>EP 1225874 A1<br>EP 1129079 A2<br>HR 20010310 A1<br>HU 0104395 A2<br>HU 0203568 A2<br>JP 2002529457 T<br>JP 2003510264 T |  | 29-05-2000<br>30-04-2001<br>30-11-2001<br>29-12-2002<br>21-05-2002<br>14-08-2001<br>18-05-2000<br>05-04-2001<br>23-10-2002<br>05-12-2001<br>17-10-2001<br>15-05-2002<br>16-12-2002<br>15-04-2003<br>05-04-2001<br>18-05-2000<br>31-07-2002<br>05-09-2001<br>30-06-2002<br>29-04-2002<br>28-02-2003<br>10-09-2002<br>18-03-2003 |

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 03/13002

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|--|------------------|-------------------------|------------------|
| WO 0122938                             | A                | NO 20011934 A           | 19-04-2001       |
|  |                  | NO 20021443 A           | 22-03-2002       |
|  |                  | NZ 517025 A             | 25-07-2003       |
|  |                  | PL 348145 A1            | 06-05-2002       |
|  |                  | SK 3762002 A3           | 10-09-2002       |
|  |                  | SK 6022001 A3           | 07-01-2002       |
|  |                  | TR 200101319 T2         | 22-10-2001       |